

Buprenorphine Prescribing Requirements and Limitations

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Introduction

In the United States, 5.7 million people over the age of 12 had an opioid use disorder (OUD) in 2023,¹ and 81,719 opioid-related overdose deaths were recorded in 2023 alone.² In addition to harming an individual's physical health (e.g., elevated risk of bloodborne infectious diseases, weakened immune system), OUD can severely disrupt a person's ability to engage with their family, work, and community.³ The cause of the overdose crisis is multifaceted,⁴ and federal and state law play critical roles in both exacerbating and ameliorating the crisis. The legal classification of opioids, punitive drug criminalization, restrictions on prescribing opioids for pain management, and the implementation of various mitigation strategies all have unique impacts on the ebb and flow of the overdose crisis.

Expanding the use of medications for opioid use disorder (MOUD), specifically agonist medications buprenorphine and methadone, is a successful mitigation strategy to reduce opioid overdose deaths. MOUD is a treatment approach using medications approved by the Food and Drug Administration (FDA) to treat OUD.⁵ The FDA has approved three medications for the treatment of OUD — methadone, buprenorphine, and naltrexone⁶ — but methadone and buprenorphine are the only two proven to save lives.^{3,7} As a partial opioid agonist, buprenorphine reduces opioid withdrawal symptoms and cravings⁸ to support an individual's recovery. Although buprenorphine is classified as a Schedule III controlled substance and has been subject to heightened regulation since its approval for the treatment of OUD in 2002, the medication can be prescribed outside of specialized treatment settings, including in primary care settings, commonly referred to as “office-based opioid treatment” or “OBOT.”⁹ This contrasts sharply with methadone, which must be dispensed through a federally certified opioid treatment program (OTP).

This policy brief provides an overview of the legal landscape of buprenorphine prescribing requirements and limitations in non-OTP practice settings as of September 1, 2024, summarizes key findings of evidence evaluating their impact on treatment access and quality, and provides policy and research recommendations moving forward. The research protocol accompanying the legal dataset created by the Center for Public Health Law Research at Temple University Beasley School of Law with the Vital Strategies Overdose Prevention Program includes additional information on the scope of state laws captured by the dataset and this policy brief.¹⁰

Legal Landscape

Because of its federal classification as a Schedule III controlled substance, buprenorphine is governed by the Controlled Substances Act (CSA). Federal regulation of buprenorphine for OUD has evolved over time, trending toward fewer restrictions to expand access to treatment.¹¹ Federal law generally requires a separate DEA registration to use certain narcotic drugs in the treatment of OUD,¹² but the Drug Addiction Treatment Act of 2000 (DATA 2000) created an exception commonly referred to as the X-Waiver.⁹



Figure 1. As of September 1, 2024, 18 states and the District of Columbia explicitly regulated buprenorphine prescribing for OUD.

The X-Waiver was a federal requirement that demanded providers undergo additional training and enrollment processes to prescribe controlled substances classified as Schedule III through V, like buprenorphine for the treatment of OUD outside of an OTP setting. This meant that prescribers were tasked with fulfilling cumbersome requirements such as administrative filings, certifications, and patient caps.⁹ In 2016, the Comprehensive Addiction and Recovery Act (CARA) expanded access, extending X-Waiver eligibility to nurse practitioners and physician assistants.^{13, 14, 15} Then, in 2018, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) further extended X-Waiver eligibility to clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists through October 2023.^{14, 16}

Regulatory hurdles to buprenorphine prescribing for OUD remained despite this expanded provider eligibility. On December 29, 2022, the CSA was again amended to entirely remove the requirement that practitioners obtain an X-Waiver to prescribe buprenorphine for OUD.¹⁷ Any practitioner with a DEA registration that includes Schedule III prescriptive authority may now prescribe buprenorphine to treat OUD.¹⁸ However, while federal law has gradually moved toward more permissive regulation of buprenorphine prescribing, practitioners must still adhere to any applicable state laws on the issue.¹⁸

State buprenorphine prescribing requirements and limitations vary, with some state laws maintaining restrictive barriers to buprenorphine access, while some states implement protective provisions for patients in treatment. As of September 1, 2024, 18 states and the District of Columbia had statutes and/or regulations that explicitly governed buprenorphine prescribing for OUD in non-OTP settings.¹⁰ These state laws are equally varied; decriminalization of buprenorphine possession, regulations surrounding initial evaluations, counseling and drug testing requirements, regulation of perceived patient “non-compliance,” tapering requirements, and dosage restrictions all differ across jurisdictions.¹⁰ Further,

some states recently added new buprenorphine prescribing laws with a more limited scope: Nevada affirmatively regulates buprenorphine prescribing by extending prescriptive authority to certain pharmacists³⁵ and South Carolina, which generally prohibits the prescribing of Schedule II or III narcotics (including buprenorphine), includes an exception for prescribing buprenorphine for OUD via telehealth when a patient is “actively enrolled in a Medication-Assisted Treatment (MAT) program with a provider who has an established physician-patient relationship.”³⁶

Notably, as of September 1, 2024,

- Twelve states explicitly incorporated federal law provisions related to the X-Waiver, which is no longer consistent with federal law.¹⁰ This compares to 16 states as of March 1, 2023.
- Twelve states and the District of Columbia required counseling for patients prescribed buprenorphine for OUD, with three states establishing a minimum frequency of counseling.¹⁰
- Thirteen states and the District of Columbia required drug testing when prescribing buprenorphine for OUD, with six of these states specifying the frequency of required testing.¹⁰
- Six states regulated both buprenorphine initiation dosages and buprenorphine maintenance dosages.¹⁰
- Eleven states regulated how a practitioner responds to patient “non-compliance.”¹⁰

In looking at the change in state buprenorphine laws over time, three states have recently removed explicit buprenorphine prescribing laws altogether: Michigan (June 26, 2023), Alabama (October 15, 2023), and Utah (January 22, 2024).¹⁰ Two other states — Florida (May 18, 2023) and Ohio (October 3, 2023) — also removed certain regulatory barriers to buprenorphine access while stopping short of full repeal. As implicitly reflected by the movement toward deregulation by federal lawmakers and explicitly reflected in recent federal guidance,¹⁹ restrictive regulations of buprenorphine prescribing for OUD create barriers to access for this lifesaving treatment. These barriers may exacerbate existing disparities in treatment outcomes among traditionally marginalized populations such as Black and Hispanic patients,²⁰

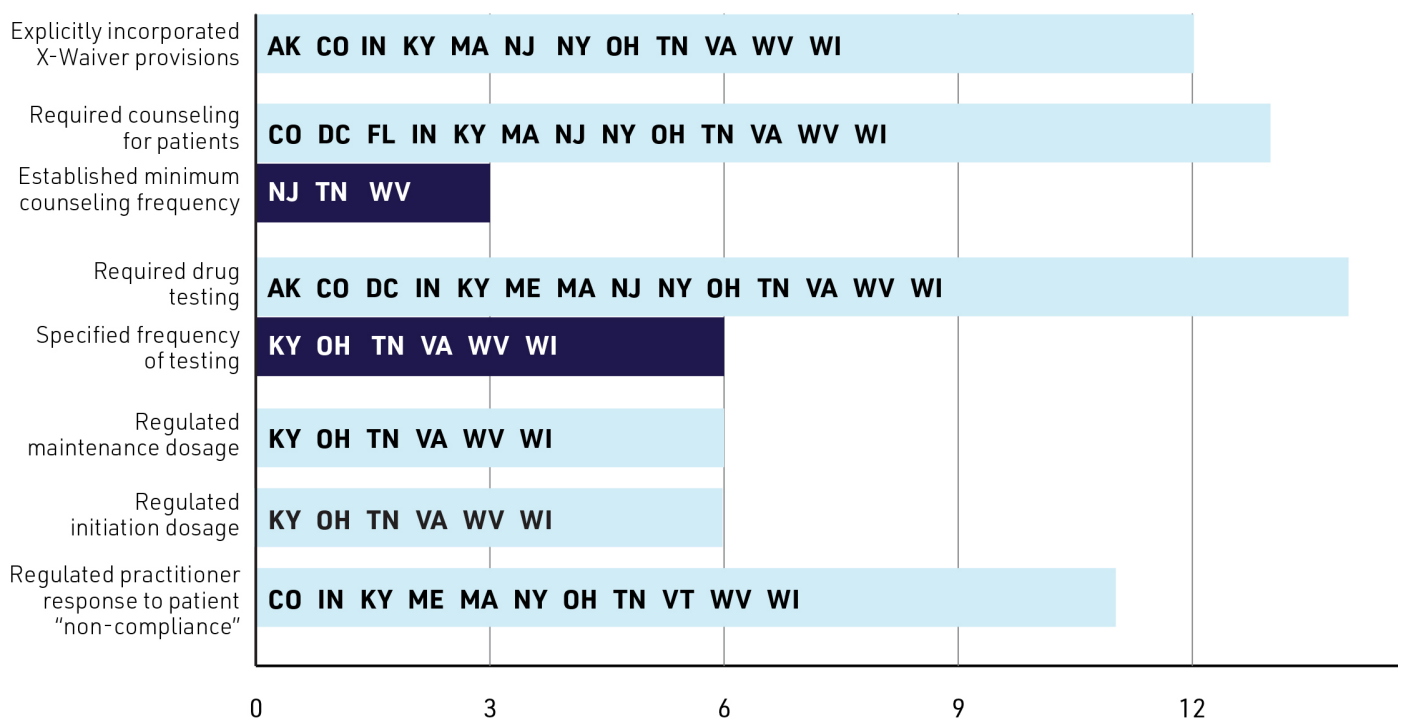


Figure 2. Notable buprenorphine provisions as of September 1, 2024

and research suggests their removal may have outsized benefits for certain racial or ethnic minorities.²¹ The repeal of the X-Waiver and associated requirements provide state policymakers with an opportunity to revisit any existing laws on the issue, and to strongly consider applying a low-barrier (also referred to as low-threshold) buprenorphine treatment framework to their policy decision-making. For example, policymakers could follow the lead of four states (IN, NY, OH, WI) that codify requirements regarding the provision of or prescription for opioid overdose reversal drugs (e.g., naloxone), or the three states (MA, NY, VT) that prohibit involuntary discharge from treatment in response to one or more types of patient non-compliance.¹⁰ Within a low-barrier buprenorphine treatment framework, policymakers can prioritize same-day treatment initiation, a harm reduction approach, flexibility, and availability of treatment in non-traditional settings.^{19, 22}

Evidence

There is strong evidentiary support for the implementation of a low-barrier buprenorphine treatment framework in policymaking.^{19, 21, 23-27} The federal government itself has acknowledged its support for lower barrier access. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) has clearly expressed that an inability to provide counseling services or referrals should not disqualify potential buprenorphine prescribers from providing treatment,¹⁸ the provision of buprenorphine should not be contingent upon a patient’s participation in counseling or other ancillary services,²⁸ and medication misuse or diversion should not automatically disqualify patients from treatment.²⁹ SAMHSA also explicitly acknowledged the removal of patient caps (via the elimination of the X-Waiver) as a means to quickly provide treatment to more patients.¹⁸ A 2023 advisory from SAMHSA went further, broadly embracing the importance of low barrier models of care and the need for “[p]olicymakers and stakeholders [...] to identify and address any inhibitors to low barrier care, including [...] regulatory policies.”¹⁹



Figure 3. As of September 1, 2024, 12 states and the District of Columbia require mandatory counseling for patients prescribed buprenorphine. Nine of those states and the District of Columbia specify the format of the mandated counseling in the law.

Research has shown that low-barrier buprenorphine treatment not only expands access to more patients, but does so equitably.²³ Specifically, quicker initiation of treatment, elimination of dosage limits, removal of mandatory counseling requirements, and safeguards against involuntary discharge for return to use (i.e., “relapse”) may improve treatment retention for more patients while narrowing treatment gaps between different socio-economic groups.^{19, 23, 25, 26, 27} Studies conducted around the COVID-19 pandemic, when a myriad of healthcare regulations were relaxed in response to the emergency, reinforce the effectiveness of lower barrier models. Improved treatment retention during that period was associated with extended prescription lengths,³⁰ reduced drug testing,³⁰ and generally less restrictive guidelines, such as expanded telemedicine use.²⁴ Research outside of the pandemic has also found no decline in treatment effectiveness²¹ or long-term treatment retention²⁵ among studied populations receiving treatment within a low-barrier framework.

Policy Recommendations

Considering the federal deregulation of buprenorphine prescribing for OUD in non-OTP settings and the research demonstrating the positive outcomes of low-barrier treatment, state policymakers should strongly consider applying a low-barrier buprenorphine treatment framework to any laws they may have on the issue. In doing so, state policymakers should:

- 1. Remove outdated references to the X-Waiver.** Policymakers in the 12 states that explicitly incorporated federal provisions related to the X-Waiver as of September 1, 2024, should consider amendment or repeal.¹⁰ Doing so would bring state law into congruity with federal law¹⁷ and better align with federal guidance and policies aimed at ensuring expanded access to buprenorphine treatment.^{11, 19, 28} Since the original publication of this data in 2024, Maine and Vermont, have removed explicit mentions of X-waiver requirements from their laws.¹⁰
- 2. Align state law with evidence-based best practices.** Research supports the contention that low-barrier buprenorphine treatment for OUD expands access and improves retention and outcomes in a more equitable manner.^{19, 23, 26} Among other policy changes, state policymakers should strongly consider removing overly burdensome regulations, such as mandatory counseling, tapering, and visit frequency requirements. Instead, policymakers should consider easing the process for initiating treatment and safeguarding against involuntary treatment termination.
- 3. Coordinate consistent policymaking across all levels of government.** As exemplified by the preservation of X-Waiver provisions in some state laws despite federal repeal, the regulation of buprenorphine prescribing can become inconsistent across different levels of government. Aligning law with evidence-based best practices should go beyond the state level, and policymakers should instead adopt a “Whole-of-Government approach” by prioritizing comprehensive, coordinated action across all levels of government to ensure effective policymaking.³¹ Increasing access to buprenorphine, for example, takes coordination vertically between federal, state, and local governments and at the same time, horizontally among different agencies and actors at one level of government. For example, state and local governments, in coordination with individual correctional facilities, can review and revise policies that hinder access to buprenorphine for OUD while incarcerated.^{31, 32}
- 4. Center and involve impacted communities in policymaking.** Research has associated better treatment retention and engagement with patient trust and prioritizing patient safety over provider concerns about diversion and misuse.^{30, 33, 34} Therefore, policymaking should intentionally include the input and participation of those directly impacted by the overdose crisis, including those living with OUD.

Research Agenda

The Buprenorphine Prescribing Requirements and Limitations dataset on LawAtlas.org provides an overview of key features of state laws regulating buprenorphine prescribing for OUD in non-OTP practice settings.¹⁰ While this dataset captures the law as it existed across the country as of March 1, 2023, through September 1, 2024, regular updates would be useful for examining changes in the law, especially as state policymakers adjust their laws in light of the federal repeal of the X-Waiver. Additionally, further evaluation of low-barrier buprenorphine treatment, as compared to outcomes under more restrictive approaches, would provide an even stronger evidentiary foundation upon which to base effective, accessible, and equitable laws and policies. Laws and policies regarding buprenorphine prescribing that fell outside of this project's scope (e.g., Medicaid policy) are also opportunities for further research. Finally, as additional states consider joining Rhode Island and Vermont in decriminalizing buprenorphine possession,¹⁰ research into the positive impacts of decriminalization becomes even more warranted.

Conclusion

With the recent removal of the X-Waiver and associated federal regulations, attention has shifted even more closely to state regulation of buprenorphine treatment. Close monitoring and effective advocacy for evidence-based policymaking is needed since, with federal deregulation, the role of state law has become even more important. With thousands of lives interrupted and ended because of the overdose crisis each year, ensuring equitable, low-barrier access to life-saving treatment must be a priority for researchers, advocates, and policymakers.

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